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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/520,936

12/19/2005

Peter Moeller-Jensen

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COLOPLAST A/S

Attention: Corporate Patents

Holteham 1

DK-3050 Humleback,

DENMARK

EXAMINER

SCHELL, LAURA C

ART UNIT

PAPER NUMBER

3767

MAIL DATE

DELIVERY MODE

04/27/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/520,936	Applicant(s) MOELLER-JENSEN ET AL.	
	Examiner LAURA C. SCHELL	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3,6-13,15-17,23,25,26 and 28-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 7-13,15-17 and 29-31 is/are allowed.
- 6) ☒ Claim(s) 3,6,23,25,26,28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 3 is rejected under 35 U.S.C. 102(b) as being anticipated by Massalsky (DE585360). Massalsky discloses an irrigation system (Figs. 1-4) comprising a reservoir (reservoir would be attached to tubes p and n) for irrigating liquid, a probe (b) for arrangement in a user, a conduit for conducting the irrigating liquid from the reservoir to the probe (the conduit is being interpreted as being comprised of portions g/l and p/n), a fixation member (d) including an inflatable cuff for fixation of the probe in the user, a pump (the pump is being interpreted as including portions u, t, r, s and h as these all appear to be what conducts the pump pressure to the different conduits) for pumping gas into the reservoir to transfer the irrigating liquid from the reservoir to the probe (it appears that air is pumped by u through t into r, through h and down through conduit p which displaces the irrigating fluid up through n, as evidenced by the arrows at

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the ends of p and n, and the fluid in n is then introduced to g where it is directed by k) and a control unit (h) which may be set in at least a cuff inflating position and a liquid transferring position (Fig. 1 discloses that knob s may be set in two different positions), said pump (u) being directly connected to the control unit (directly connected to h via t), said conduit including a first part connecting the control unit with the probe (first part is g which connects h with the probe) and a second part connecting the reservoir with the control unit (second part p/n connect the reservoir with the control unit h), each of said first and second parts including a gas conducting tube and an irrigating liquid conducting tube (first part has two separate tubes g and l and the second part has the two separate tubes p and n).

Claim 6 is rejected under 35 U.S.C. 102(b) as being anticipated by Massalsky (DE585360). Massalsky discloses an irrigation system (Figs. 1-4) comprising a reservoir (reservoir would be attached to tubes p and n) for irrigating liquid, a probe (b) for arrangement in a user, a conduit (n) for conducting the irrigating liquid from the reservoir to the probe, a fixation member (d) including an inflatable cuff for fixation of the probe in the user, a pump (the pump is being interpreted as including portions u, t, r, s and h as these all appear to be what conducts the pump pressure to the different conduits) for pumping gas into the reservoir to transfer the irrigating liquid from the reservoir to the probe (it appears that air is pumped by u through t into r, through h and down through conduit p which displaces the irrigating fluid up through n, as evidenced

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by the arrows at the ends of p and n, and the fluid in n is then introduced to g where it is directed by controller k) and a control unit (k) which may be set in at least three different positions including an inactive position (Fig. 4 discloses the cuff inflating position, however if the control unit were turned to an intermediate position such that all the channels were blocked, such as if the knob x in Fig. 4 were rotated 45 degrees either clockwise or counterclockwise, the control unit could be interpreted as being in an inactive position as all the flow channels would be blocked), a cuff inflating position in which gas is pumped into the inflatable cuff (when fluid flows through conduit i) and a liquid transferring position in which gas is pumped into the reservoir and irrigating liquid is transferred from the reservoir to the probe (when fluid flows through g to the probe b).

Claims 25 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Massalsky (DE585360). Massalsky discloses an irrigation system (Figs. 1-4) comprising a reservoir (reservoir would be attached to tubes p and n) for irrigating liquid, a probe (b) for arrangement in a user, a conduit (n) for conducting the irrigating liquid from the reservoir to the probe, a fixation member (d) including an inflatable cuff for fixation of the probe in the user, a pump (the pump is being interpreted as including portions u, t, r, s and h as these all appear to be what conducts the pump pressure to the different conduits) for pumping gas into the reservoir to transfer the irrigating liquid from the reservoir to the probe (it appears that air is pumped by u through t into r,

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through h and down through conduit p which displaces the irrigating fluid up through n, as evidenced by the arrows at the ends of p and n, and the fluid in n is then introduced to g where it is directed by controller k) and a control unit (k) which may be set in at least two different positions (Fig. 4 discloses that K may be set such that fluid from g flows into i, or it may be set such that fluid from g flows through k and into the second part of g and thus into the probe b) that include a cuff inflating position (when fluid flows through i) and a liquid transferring position (when fluid flows through g to the probe b), said control unit including three flexible tubes connected to a pumping element at one end (tubes g, p and n are all connected to h which is part of the pumping element), the first tube being connected to a gas outlet (gas pumped by u/h exits through p so p is therefore connected to some sort of gas outlet), the second tube being connected to the reservoir (n appears to be connected to the reservoir) and the third tube being connected to the inflatable cuff (g is connected to the inflatable cuff via passageway i in Fig. 4).

In reference to claim 28, Massalsky discloses that the tubes are individually compressed to prevent fluid flow there through such that one of the tubes allows fluid to flow there through at the same time that another of the tubes prevents fluid flow there through (Figs. 1-4).

Claim Rejections - 35 USC § 103

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 23 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Massalsky (DE585360). Massalsky discloses the device substantially as claimed including an irrigation system (Figs. 1-4) comprising a reservoir (reservoir would be attached to tubes p and n) for irrigating liquid, a probe (b) for arrangement in a user, a conduit (n) for conducting the irrigating liquid from the reservoir to the probe, a fixation member (d) including an inflatable cuff for fixation of the probe in the user, a pump (the pump is being interpreted as including portions u, t, r, s and h as these all appear to be what conducts the pump pressure to the different conduits) for pumping gas into the reservoir to transfer the irrigating liquid from the reservoir to the probe (it appears that air is pumped by u through t into r, through h and down through conduit p which displaces the irrigating fluid up through n, as evidenced by the arrows at the ends of p and n, and the fluid in n is then introduced to g where it is directed by controller k) and a

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control unit (k) which may be set in at least two different positions (Fig. 4 discloses that K may be set such that fluid from g flows into i, or it may be set such that fluid from g flows through k and into the second part of g and thus into the probe b) that include a cuff inflating position (when fluid flows through i) and a liquid transferring position (when fluid flows through g to the probe b), the pump being hand powered (Fig. 1) and being deactivated when the control unit is set in a first position (if the control unit k in Fig. 4 is rotated 45 degrees either clockwise or counterclockwise, the flow channels will be blocked and the device will be essentially deactivated) and being activated when the control unit is set in a second position (when the control unit in Fig. 4 is set such that the channels are aligned to allow flow, then the device is activated). Massalsky, however, does not disclose that the pump is powered by an external device or that the device is automatically activated. It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the pump of Massalsky such that the pump was automatic and the device is automatically activated, since it has been held that broadly providing a mechanical or automatic means to replace manual activity which has accomplished the same result involves only routine skill in the art. In re Venner, 120 USPQ 192.

In reference to claim 26, Massalsky discloses that the device substantially as claimed except for the external device powering said pump being electrically or pneumatically operated. It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the pump of Massalsky such that the pump was electrically powered/operated, since it has been held that broadly providing a

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mechanical or automatic means to replace manual activity which has accomplished the same result involves only routine skill in the art. In re Venner, 120 USPQ 192.

Allowable Subject Matter

Claims 7-13, 15-17, 29-31 are allowed. The allowability of claims 3, 6, 23, 25, 26 and 28 is withdrawn after reviewing the claims and determining that the Massalsky reference should be applied as prior art.

The following is a statement of reasons for the indication of allowable subject matter: Independent claim 7 as well as dependent claims 8-12 are allowed because the subject matter that could not be found is a control unit comprised of a first disc, second disc and intermediate disc, the intermediate disc being rotatable with respect to the first and second discs, the rotation setting the cuff inflating and liquid transferring positions, in combination with the other elements of the claims.

Independent claim 13 as well as dependent claims 15-17 are allowed because the subject matter of dependent claim 14, which was not found, was added to independent claim 13, in combination with the other elements of the claims.

Independent claim 29 and dependent claims 30 and 31 are allowed because the subject matter that could not be found is the arrangement of the five canals within the cylindrical element and the arrangement of the five canals in relation to each other, in combination with the other elements of the claims.

Response to Arguments

Applicant's arguments with respect to claims 3, 6-13, 15-17, 23, 25, 26, 28-31 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA C. SCHELL whose telephone number is (571)272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Laura C Schell/

Examiner, Art Unit 3767

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767